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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,768	07/08/2003	Lorraine Faxon Meisner	41758-P002D1C1	8047
39770	7590	06/13/2006	EXAMINER	
SANFORD E. WARREN, JR. P.O. BOX 50784 DALLAS, TX 75201			FLOOD, MICHELE C	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/614,768

Applicant(s)

MEISNER, LORRAINE FAXON

Examiner

Michele Flood

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 102-117 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 102-117 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/12/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on March 8, 2006 with Applicant's cancellation of non-elected Claims 118-123.

Election/Restrictions

Applicant's election without traverse of Group I, Claims 102-117, in the reply filed on March 8, 2006 is acknowledged.

Claims 102-117 are under examination.

Drawings

The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81(c). No new matter may be introduced in the required drawing. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). In the instant case, Applicant refers to Figure 1a and Figure 1b, on page 11. However, these figures are missing from the present application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 110-117 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 110 recites the limitation “the formation” in line 2. There is insufficient antecedent basis for this limitation in the claim. It appears that Applicant has misspelled formulation. Appropriate correction is required.

The metes and bounds of Claim 110, line 2, are rendered uncertain by the phrase “wherein the formation may be suitable for topical application on human skin” because either the composition is suitable or is not suitable for topical application on human skin. The lack of clarity renders the claim ambiguous.

Claim 110 recites “the area” in line 3. There is insufficient antecedent basis for this limitation in the claim. Applicant may overcome the rejection by replacing “the” with an.

Claim 110 recites “the production” in line 4. There is insufficient antecedent basis for this limitation in the claim. Applicant may overcome the rejection by deleting “the”.

Claim 110 recites “the proliferation” in line 4. There is insufficient antecedent basis for this limitation in the claim. Applicant may overcome the rejection by deleting “the”.

Claim 110 recites "the production" in line 4. There is insufficient antecedent basis for this limitation in the claim. Applicant may overcome the rejection by deleting "the".

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Objections

Claims 104-107, 110, 112 and 116 are objected to because of the following informalities: There are apparent misspellings in each of the aforementioned claims.

Applicant may overcome the objection by:

Replacing "keraloytic" with keratolytic in each of Claims 104-106;

Replacing "salicyclic" with salicylic in Claim 107;

Replacing "on" with one, in Claim 110, line 4; and,

Replacing "on" with one, in Claims 112 and 116.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 102, 103 and 110-115 are rejected under 35 U.S.C. 102(b or e) as being anticipated by Vanden Berghe (N or AA, US 6,495,531 B2).

Applicant claims an anti-inflammatory and anti-pruritic topical skin preparation comprising glucosamine in an emollient base. Applicant further claims the preparation of claim 102, wherein the topical skin preparation is used to treat insect bites on human

skin. Applicant further claims the preparation of claim 102, wherein the topical preparation is used to treat insect bites on human skin. Applicant claims an anti-inflammatory and anti-pruritic topical skin preparation comprising glucosamine in an emollient base, wherein the formulation may be suitable for topical application on human skin, and further wherein the formulation at least partially suppresses, local to an area of topical application production of at least one cytokine that stimulates proliferation of apoptosis resistant keratinocytes.

Vanden Berghe teaches an anti-inflammatory, anti-pruritic and pain-relieving topical skin preparation comprising glucosamine in an emollient base, which is suitable for topical application to human skin. See Column 3, lines 25-59; and, Column 1, lines 63-66, wherein Vanden Berghe teaches the anti-inflammatory activity associated with the use of glucosamine.

Vanden Berghe neither teaches the referenced composition as a composition for use in the treatment of insect bites on human skin nor as having the claimed functional effect for at least partially suppressing, local to an area of topical application, the production of at least one cytokine, including interleukin-2 and/or interferon gamma. However, the topical skin preparation taught by Vanden Berghe comprises each of the ingredients instantly claimed by Applicant; and, therefore the claim-designated functional effects are considered inherent to the composition taught by Vanden Berghe.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195

USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

The reference anticipates the claimed subject matter.

Claims 102-106, 107 and 110-115 are rejected under 35 U.S.C. 102(b) as being anticipated by Pollock (A*).

Applicant's claimed invention of Claims 102, 103 and 110-115 was set forth above. Applicant further claims the preparation of claim 103 or claim 110, further including a keratolytic. Applicant further claims the preparation of claim 104, wherein the keratolytic includes a salicylate. Applicant further claims the preparation of claim 105, wherein the salicylate includes salicylic acid.

Pollock teaches a topical skin preparation suitable for topical application to the human skin comprising glucosamine in an emollient base, ascorbic acid (an anti-oxidant), and a glycolic acid (keratolytic agent, such as salicylic acid). The composition taught by Pollock provides both anti-inflammatory and anti-pruritic functional effects. See Column 2, line 60 to Column 2, line 45. In Column 3, lines 24-33, Pollock teaches that salicylic acid is useful as a keratolytic agent in the making of the referenced topical skin preparation. Pollock further teaches that the referenced composition is useful in treating acne. See patent claims 5 and 11.

Pollock neither teaches the referenced composition as a composition for use in the treatment of insect bites on human skin nor as having the claimed functional effect for at least partially suppressing, local to an area of topical application, the production of at least one cytokine, including interleukin-2 and/or interferon gamma. However, the

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topical skin preparation taught by Pollock comprises each of the ingredients instantly claimed by Applicant; and, therefore the claim-designated functional effects are considered inherent to the composition taught by Pollock

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

The reference anticipates the claimed subject matter.

Claims 102-104, 106, 107 and 110-115 are rejected under 35 U.S.C. 102(b) as being anticipated by Schinitski (NN, EP 0281812).

Applicant's claimed invention was set forth above.

Schinitski teaches an anti-inflammatory topical composition comprising glucosamine, salicylic acid (a keratolytic agent), and zinc oxide in a topical ointment base, which is useful for the treatment of acne on humans, in Column 6, lines 51-54.

Schinitski neither teaches the referenced composition as a composition as having anti-pruritic activity, nor for use in the treatment of insect bites on human skin nor as having the claimed functional effect for at least partially suppressing, local to an area of topical application, the production of at least one cytokine, including interleukin-2 and/or interferon gamma. However, the topical skin preparation taught by Schinitski comprises each of the ingredients instantly claimed by Applicant; and, therefore the

claim-designated functional effects are considered inherent to the composition taught by Schinitzki.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

The reference anticipates the claimed subject matter.

Claims 102-104, 108 and 110-116 are rejected under 35 U.S.C. 102(b) as being anticipated by Noel (BB, US 5,401,773).

Applicant's claimed invention of Claims 102-104 and 110-116 was set forth above. Applicant further claims the preparation of claim 103, further including at least one antioxidant from an herbal source.

Noel teaches an anti-inflammatory composition for topical application to the human skin comprising glucosamine, gamma orizanol (an antioxidant from an herbal source) and lactic acid (a keratolytic) in an emollient base (moisturizing cream). See Example 6, in Column 4, lines 50-67. The composition taught by Noel is used for treating skin suffering from greasy or seborrheic skin, comedones and acne. In Column 3, lines 11- 26, Noel teaches that the referenced composition have comedolytic and keratolytic activity.

Noel neither teaches the referenced composition as a composition having anti-pruritic activity nor for use in the treatment of insect bites on human skin nor as having

the claimed functional effect for at least partially suppressing, local to an area of topical application, the production of at least one cytokine, including interleukin-2 and/or interferon gamma. However, the topical skin preparation taught by Noel comprises each of the ingredients instantly claimed by Applicant; and, therefore the claim-designated functional effects are considered inherent to the composition taught by Noel.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 102-104, 106, 107 and 110-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanden Berghe (N or US 6,495,531 B2) in view of Winter (W).

Applicant's claimed invention was set forth above.

The teachings of Vanden Berghe were set forth above. Vanden Berghe teaches the instantly claimed invention except for wherein the preparation further includes a

keratolytic and wherein the keratolytic includes the salicylate, salicylic acid. However, it would have been obvious to one of ordinary skill in the art, and one of ordinary skill in the art would have been motivated and would have had a reasonable expectation of success to add the claim-designated salicylic acid to the composition taught by Vanden Berghe to provide the instantly claimed invention because at the time the invention was made Winter taught that salicylic acid was useful as a keratolytic agent in the preparation of topical skin compositions due to its beneficial anti-inflammatory, anti-pruritic, astringent, fungicidal and skin sloughing functional effects; and, in Column 2, lines 58-65, Vanden Berghe taught that the referenced topical skin preparation could further comprise other pain or itch relieving compounds, as anti-inflammatory agents.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the claimed ingredient in the making of the claimed composition because it is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinton*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 102, 103 and 108-117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanden Berghe (N) in view of Erdelmeir et al. (V).

Applicant's claimed invention of Claims 102, 103 and 110-116 was set forth above. Applicant further claims the preparation of claim 103 or claim 110, further including at least one antioxidant from an herbal source. Applicant further claims the preparation of claim 108 or claim 116, wherein the herbal source is witch hazel.

The teachings of Vanden Berghe are set forth above. Vanden Berghe teaches the instantly claimed invention except for witch hazel as a source of at least one herbal antioxidant further included in the instantly claimed topical skin preparation. However, it would have been obvious to one of ordinary skill in the art to an antioxidant obtained from witch hazel to provide the instantly claimed invention because at the time the invention was made Erdelmeir taught an antioxidant obtained from *Hamamelis virginiana* (witch hazel) having radical scavenging effect, as well as anti-viral and anti-inflammatory activities. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the witch hazel antioxidant taught by Erdelmeir to the topical skin preparation taught by Vanden Berghe to provide the instantly claimed invention because Erdelmeir taught that the antioxidant obtained from the witch hazel plant had significant antiviral activity against Herpes simplex virus, the ultraviolet antioxidant concentrate displayed radical scavenging properties, inhibited alpha-glucosidase as well as human leukocyte elastase and exhibited strong anti-inflammatory effects in an oil based test composition; and, Vanden Berghe taught that the referenced topical

emollient based glucosamine composition was useful in the treatment of herpes simplex virus infection in humans.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the claimed ingredient in the making of the claimed composition because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 102-105 and 110-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanden Berghe (N) in view of Navarro (B*), and further in view of Hebborn (C*).

Applicant's claimed invention of Claims 102-104 and 110-115. Applicant further claims the method of claim 104, wherein the keratolytic agent includes coal tar.

The teachings of Vanden Berghe were set forth above. Vanden Berghe teaches the instantly claimed invention except for further including coat tar extract as a keratolytic. However, it would have been obvious to one of ordinary skill in the art to

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add the instantly claimed ingredient to the composition taught by Vanden Berghe to teach the instantly claimed invention because at the time the invention was made Navarro taught that it was old and well known in the art to use coal tar in the making of compositions for the therapeutic treatment of various skin diseases, such as eczema. Like, Navarro, Hebborn also taught coal tar as a useful ingredient in the making of anti-eczema compositions. Hebborn further taught, "Some of the therapeutic dermatologic effects of tar, and the constituents that are thought to be responsible for producing them, include the following: (1) Antipruritic and antibacterial: phenols, cresol, and naphthalene; (2) Keratoplastic (normalizing the production of keratin): methylnaphthalene, dinaphthalene, xlenol, and naphthol." At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the coal tar extract taught by Navarro to the composition taught by Vanden Berghe to provide the instantly claimed topical skin preparation because Navarro taught that the referenced coal tar extract was safer than other prior coal tar extracts and that it was useful in the making of therapeutic topical skin formulations in an emollient; and Hebborn taught that coal tar has antipruritic, keratolytic and keratoplastic activities and is useful in the making of topical formulations intended for the treatment of human skin diseases, such as eczema; and Vanden Berghe teaches that the ingredients contained in the referenced composition is useful as a topical skin preparation for the treatment of eczema, in Column 5, under "Example 10".

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the claimed ingredient in the making of the claimed composition because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 102-104, 106, 107 and 110-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pollock (A*). Claims 102-104, 106, 107 and 110-115 were rejected under 35 U.S.C. 102(b); however, the claims are also rejected herein for reasons made apparent as set forth immediately below.

Applicant's claimed invention was set forth above.

The teachings of Pollock were set forth above. While Pollock teaches an anti-inflammatory and anti-pruritic topical skin preparation comprising glucosamine in an emollient base, and further comprising an alpha- and/or beta hydroxy acid as a keratolytic agent; and while Pollock teaches salicylic acid as a beta hydroxy acid

having keratolytic activity that is useful in the making of the referenced composition; and while the patent claims teach a topical skin preparation comprising glucosamine, an antioxidant, and a keratolytic alpha and/or beta hydroxy acid, Pollock does not expressly teach a composition comprising glucosamine, an antioxidant, and salicylic acid as a keratolytic agent *per se*. Nonetheless, in the alternative, even if the referenced composition is not the same as the composition disclosed by Applicant, given the slight differences in the prior art composition and the composition instantly claimed by Applicant, at the time the invention was made, the instantly claimed invention still would have been *prima facie* obvious to one of ordinary skill in the art practicing the invention within the meaning of 35 USC 103, given the teachings of Pollock. For instance, Applicant may argue that Pollock does not expressly teach a composition comprising salicylic acid. However, it would have been obvious to one of ordinary skill in the art to incorporate salicylic acid into the composition taught by Pollock to provide the instantly claimed invention because at the time the invention was made Pollock taught salicylic acid as a beta-hydroxy acid useful in the making of the prior art reference. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to incorporate salicylic acid into the composition taught by Pollock to provide the instantly claimed topical skin preparation because Pollock taught that alpha and/or beta hydroxy acids, such as the instantly claimed salicylic acid, provide the functional effects of exfoliating away skin dead skin cells and maintaining moisture in the human skin cells; and, Pollock suggested that alpha and beta hydroxy acids as functional

equivalents useful in the making of the prior art composition. Thus, the instantly claimed invention would have been no more than a matter of judicious choice to the skilled artisan practicing the invention to substitute one functional equivalent for the other, given that Pollock taught that both alpha and beta hydroxy acids were equally effective as keratolytic agents in the making of the prior anti-inflammatory and anti-pruritic topical skin preparation intended for human use

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 102-104 and 106, 107, 108, 109 and 110-117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pollock (A*) in view of Masaki et al. (U).

Applicant's claimed invention was set forth above.

The teachings of Pollock were set forth above. Pollock teaches the instantly claimed invention except for further including an antioxidant obtained from an herbal source, wherein the herbal source is witch hazel. Although the composition taught by Pollock comprises an antioxidant, it is unclear from the teachings of Pollock whether the source of the antioxidant is obtained from an herbal source. Nonetheless, it would have been obvious to one of ordinary skill in the art to add an antioxidant obtained from witch hazel to the composition taught by Pollock to provide the instantly claimed invention because at the time the invention was made Masaki taught an antioxidant obtained from *Hamamelis virginiana* (witch hazel) exhibiting significant oxygen scavenging activity. At

the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the witch hazel antioxidant taught by Masaki to the composition taught by Pollock to provide the instantly claimed invention because Masaki demonstrated a witch hazel oxidant, particularly a hamamelitannin fraction, as a potent scavenger against superoxide anion radicals, hydroxyl radicals, singlet oxygens, lipid peroxides and organic radicals in the chemical aspect, and against cell damage induced by superoxide anion radicals, hydroxyl radicals, and singlet oxygens in the biological aspect; and, like Pollock, Masaki suggests that prevention of photoaging could be achieved by active oxygen-scavenger, such as the instantly claimed witch hazel antioxidant and the antioxidants comprising the composition taught by Pollock.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the claimed ingredient in the making of the claimed composition because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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May 30, 2006


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